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Giulio Nicita

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EXAMINER

HARRIS, CARRIE R

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

11/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,144	<b>Applicant(s)</b> NICITA, GIULIO	
	<b>Examiner</b> Carrie Harris	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                                  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application                        |
| Paper No(s)/Mail Date <u>31 January 2005</u> .   | 6) <input checked="" type="checkbox"/> Other: <u>Notice of Non-compliant Amendment</u> . |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 1 August 2002. It is noted, however, that applicant has not filed a certified copy of the FI2002A000145 application as required by 35 U.S.C. 119(b).

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cleft that longitudinally cuts both the front and rear portions, the cleft that transversely cuts the right central portion, and the cleft that transversely cuts the left central portion must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: I. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The disclosure is objected to because of the following informalities: numerical distances recited in line 2 of page 7 lack units.

Appropriate correction is required.

***Claim Objections***

5. **Claims 31-36** are objected to because of the following informalities:
- Claims 31-36 include reference characters which are enclosed within parentheses. The use of reference characters is considered as having no effect on the scope of the claims. Since the reference characters are not afforded patentable weight, the reference characters enclosed within parentheses should be deleted from the claims.
  - Claim 31 reads "characterised" and should read --characterized--.
6. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 31-61** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites the limitation "may be distinguished" in line 3, which renders the claim indefinite as the limitations following "may be" are not positively claimed. The use of the term "may" is considered equivalent to the term "possibly". The Examiner suggests that Applicant amend the phrase "in which may be distinguished" to read --

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further comprising--, --comprises--, --comprising--, --consisting of--, or a similar transitional phrase.

Claim 31 recites the limitation "the two arms" in line 10, which renders the claim indefinite as it is unclear which two of the four arms recited this limitation is referencing.

The recitation of "said material of organic origin" in claim 38 renders this claim indefinite as "materials of organic origin" is not positively required in claim 37.

The recitation of "said material of a synthetic nature" in claims 40 and 41 render these claims indefinite as "materials of a synthetic nature" are not positively required in claim 37.

Claims 42 and 43 are indefinite as they recite numerical values that do not have accompanying units. Claim 42 is interpreted as "between 0.06 cm and 0.1 cm", and claim 43 is interpreted as "0.08 cm".

Claim 44 recites the limitations "the length a-a", "the length b-b", "the length c-c", "the length b-c", "the length d-y", "the total length d-z", "the length e-f", "the distance h-h", "the distance g-g", "the distance i-i", and "the length h-i". There is insufficient antecedent basis for these limitations in the claim.

Claim 46 recites the limitations "the length a-a", "the length b-b", "the length c-c", "the length b-c", "the length d-y", "the total length d-z", "the distance y-x", "the distance x-e", "the length e-f", "the distance h-h", "the distance g-g", "the distance i-i", and "the length h-i". There is insufficient antecedent basis for these limitations in the claim.

Claims 45 and 47 recite the limitations “for patients with a large body size” and “for patients with a small size”. These limitations are unclear as “a large body size” and “small size” are undefined.

Claims 48-53 and 60 include the limitation “selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopic surgery, and mini-invasive surgery”, which are improper attempts at Markush Group limitations, see MPEP 2173.05(h) and Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931). The Examiner suggests that Applicant amend the claims to include the phrase --selected from a group consisting of--.

Claims 54-59 and 61 recite the “tendinous arch of the levator ani”. This anatomical structure cannot be found in common anatomical texts. Therefore the Examiner requests that Applicant explain the location in the body of the anatomical structure in question.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 31-33, 35-37, 40, 41, and 44-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil).

Regarding **claim 31**, Landgrebe et al. teaches a flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs (col. 2, lines 6-11), having a central body (*Figure 1, base, 1*) with a trapezoid shape with four arms (*Figure 1, projections, 5-8*) (col. 2, lines 30-35, 37, 42, 45-46, and 55), in which may be distinguished: a front portion (*Figure 1, region of corner, 2*) corresponding to the smaller base of the trapezium (col. 2, lines 30-35), from the ends of which branch off two arms (*projections, 5 and 6*) (col. 2, lines 37 and 42); a central portion (*Figure 1, central portion of base, 1*) corresponding to the central part of the trapezium; a rear portion (*Figure 1, portion between corners, 3 and 4*) corresponding to the larger base of the trapezium (col. 2, lines 30-35), from the ends of which branch off two arms (*projections, 7 and 8*) diverging from each other and parallel to the sides of the trapezium (col. 2, lines 45-46 and 55); characterized in that the said two arms (*projections, 5 and 6*) branch off from the front portion (region of *corner, 2*) in opposite directions and are coaxial with each other and parallel to said smaller base (These arms are coaxial when the device is folded in half longitudinally. These arms are also considered to be parallel to the side portions of the smaller base of the trapezium; see *Figure 1*). Landgrebe et al. does not teach that the central portion has a hole and a cleft.

However, Rehil teaches a flat implantable device comprising a central portion (*Figure 1, patch, 9*) that has a central hole (*Figure 1, hole in patch, 1*) from which starts a cleft (*Figure 1, slit, 14*) (col. 4, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the hole and cleft of Rehil in the device of Landgrebe et al., because a hole and a cleft allow the implant to



surround the desired prolapsed organ to provide additional support (Rehil, col. 4, lines 30-34).

Regarding **claim 32**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31 above (see discussion for claim 31). Landgrebe et al. and Rehil teach that said cleft (Rehil, *Figure 1, slit, 14*) longitudinally cuts the rear portion (Landgrebe et al., *Figure 1, portion between corners, 3 and 4*) of said central body (Landgrebe et al., *Figure 1, base, 1*) (see Rehil, *Figure 1*).

Regarding **claim 33**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31 above (see discussion for claim 31). Landgrebe et al. and Rehil teach that said cleft (Rehil, *Figure 1, slit, 14*) longitudinally cuts the front portion (Landgrebe et al., *Figure 1, region of corner, 2*) of said central body (Landgrebe et al., *Figure 1, base, 1*) (see Rehil, *Figure 1*).

Regarding **claim 35**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31 above (see discussion for claim 31). Landgrebe et al. and Rehil teach that said cleft (Rehil, *Figure 1, slit, 14*) transversely cuts the right central portion (Landgrebe et al., *Figure 1, central portion of base, 1*) of said central body (Landgrebe et al., *Figure 1, base, 1*) (see Rehil, *Figure 1*).

Regarding **claim 36**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31 above (see discussion for claim 31). Landgrebe et al. and Rehil teach that said cleft (Rehil, *Figure 1, slit, 14*) transversely cuts the left central portion (Landgrebe et al., *Figure 1, central portion of base, 1*) of said central body (Landgrebe et al., *Figure 1, base, 1*) (see Rehil, *Figure 1*).

Regarding **claims 37, 40, and 41**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31 above (see discussion for claim 31). Landgrebe et al. teaches that said material with a reticular or laminar structure is a mixture of monofilament polypropylene and polyglactin (col. 3, lines 12-27).

Regarding **claims 44-47**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31 above (see discussion for claim 31). Landgrebe et al. teaches that the implant is intended to achieve anatomically adequate and permanent displacement of the bladder neck, and to correct pelvic prolapse in that vicinity (col. 1, lines 11-18). Landgrebe et al. also teaches that the area of the trapezium (*Figure 1*, base, 1) is about 30-50 cm<sup>2</sup> (col. 2, lines 30-35). Landgrebe et al. and Rehil are silent as to the specific dimensions of each portion of the implant.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the dimensions of Landgrebe et al. and Rehil to match those specified in claims 44-47 because Applicant has not disclosed that an implant having those particularly claimed dimensions versus dimensions outside of those specified ranges provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an implant of the dimensions described in Landgrebe et al. and Rehil because it will provide adequate and secure support to prolapsed organs to correct anatomical deficiencies (Landgrebe et al., col. 1, lines 11-18; Rehil, col. 4, lines 30-34). Therefore, it

would have been an obvious matter of design choice to modify Landgrebe et al. and Rehil to obtain the invention as specified in claim 44-47.

11. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as applied to claim 31 above, and further in view of U.S. Patent Application Publication No. 2003/0212460 (Darois et al.).

Regarding **claim 34**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 31 above (see discussion for claim 31). Landgrebe et al. and Rehil do not teach that said cleft longitudinally cuts both the front and rear portions.

However, Darois et al. teaches a flat implantable device (*Figure 16, prosthesis, 20*) comprising a central body having a cleft that longitudinally cuts both the front portion and the rear portion of the central body (see *Figure 16*; [0053]; [0106]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the cleft in the device of Landgrebe et al. and Rehil such that the cleft longitudinally cuts both the front and rear portions of the central body as taught by Darois et al., because a cleft that longitudinally cuts both the front and rear portions of the central body and a cleft that only cuts either the front or rear portion of the central body are substitutable as long as the device securely wraps around the organ to be supported when implanted.

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12. **Claims 38 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as applied to claim 37 above, and further in view of U.S. Patent No. 6,355,065 (Gabbay).

Regarding **claims 38 and 39**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 37 above (see discussion for claim 37). Landgrebe et al. and Rehil do not teach that the material is bovine pericardium.

However, Gabbay teaches a flat implantable device (*Figure 1, apparatus, 10*) that is composed of bovine pericardium that has been treated with glutaraldehyde and heparin (col. 2, lines 40-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to form the device of Landgrebe et al. and Rehil from bovine pericardium that has been treated with glutaraldehyde and heparin as taught by Gabbay, because bovine pericardium treated in this manner is substitutable for a synthetic material as it encourages tissue ingrowth to further anchor the implant.

13. **Claims 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as applied to claim 37 above, and further in view of U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.).

Regarding **claims 42 and 43**, Landgrebe et al. in view of Rehil teaches all the limitations of claim 37 above (see discussion for claim 37). Landgrebe et al. and Rehil are silent as to the pore size of the material.

However, Thierfelder et al. teaches a flat implantable device (*Figure 1, article, 10*) that is formed from polyester mesh, and has holes having diameter comprised between 0.01 cm and 0.05 cm (about 1.016 mm to about 1.397 mm, [0097]), necessarily at a distance from each other of between 0.06 cm and 0.1 cm (pore density is between 50 and 400 pores per square inch, [0097]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Landgrebe et al. and Rehil to have the pore size and pore density of Thierfelder et al., because pores of this size and density encourage tissue ingrowth to further secure the implant in the tissue (Thierfelder et al., [0056], [0097]).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide holes having a diameter of 0.03 cm at a distance of 0.08 cm from each other because Applicant has not disclosed that a specific hole diameter of 0.03 cm and a specific distance of 0.08 cm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with holes having a diameter of about 0.01 cm at a density of about 240 holes per square inch because they would encourage and allow tissue to grow into the implant to further secure the implant to the surrounding tissue (Thierfelder et al., [0056]; [0097]). Therefore, it would have been an obvious matter of design choice to modify Landgrebe et al., Rehil, and Thierfelder et al. to obtain the invention as specified in claim 43.

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14. **Claims 48-50, 52, 53, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) as applied to claims 31-33, 35, or 36 above, and further in view of U.S. Patent Application Publication No. 2002/0107430 (Neisz et al.).

Regarding **claims 48-50, 52, 53, and 60**, Landgrebe et al. in view of Rehil teaches all the limitations of claims 31-33, 35, 36, or 44 above (see discussion for claims 31-33, 35, 36, or 44). Landgrebe et al. teaches that the device is implanted to correct female genital prolapse (The vagina is necessarily part of female genitalia as referred to by “decensus genitalis and prolapse”, col. 1, lines 11-18). Landgrebe et al. and Rehil do not teach that the device is inserted through the vaginal cavity.

However, Neisz et al. teaches a method for surgically implanting a flat implantable device (*Figure 41, sling*, 42p) in a non-hysterectomized patient suffering a prolapse of the vaginal vault ([0250]), comprising inserting the said device (*sling*, 42p) into the vaginal cavity of the patient by means of a surgical approach that is mixed vaginal/abdominal surgery ([0215]; [0216]; [0250]). It would have been obvious to one of ordinary skill in the art at the time of the invention to implant the device of Landgrebe et al. and Rehil in the manner taught by Neisz et al., because insertion through the vaginal wall instead of an abdominal incision is less invasive, thus lessens recovery time and pain for the patient.

15. **Claim 51** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 774 240 (Landgrebe et al.) in view of U.S. Patent No. 6,436,030 (Rehil) and U.S. Patent

Application Publication No. 2003/0212460 (Darois et al.) as applied to claim 34 above, and further in view of U.S. Patent Application Publication No. 2002/0107430 (Neisz et al.).

Regarding **claim 51**, Landgrebe et al. in view of Rehil and Darois et al. teaches all the limitations of claim 34 above (see discussion for claim 34). Landgrebe et al. teaches that the device is implanted to correct female genital prolapse (The vaginal is necessarily part of female genitalia, col. 1, lines 11-18). Landgrebe et al. and Rehil do not teach that the device is inserted through the vaginal cavity.

However, Neisz et al. teaches a method for surgically implanting a flat implantable device (*Figure 41, sling*, 42p) in a non-hysterectomized patient suffering a prolapse of the vaginal vault ([0250]), comprising inserting the said device (*sling*, 42p) into the vaginal cavity of the patient by means of a surgical approach that is mixed vaginal/abdominal surgery ([0215]; [0216]; [0250]). It would have been obvious to one of ordinary skill in the art at the time of the invention to implant the device of Landgrebe et al., Rehil, and Darois et al. in the manner taught by Neisz et al., because insertion through the vaginal wall instead of an abdominal incision is less invasive, thus lessens recovery time and pain for the patient.

### ***Response to Amendment***

16. The amendment to the claims filed on 17 August 2006 does not comply with the requirements of 37 CFR 1.121(c) because the claim text altered lacks the appropriate

markings. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of “canceled” or “not entered” may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended,” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of “currently amended,” or “withdrawn” if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn—currently amended.”

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of “original,” “withdrawn” or “previously presented” will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of “withdrawn” or “previously presented.” Any claim added by amendment must be indicated with the status of “new” and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*



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(i) No claim text shall be presented for any claim in the claim listing with the status of “canceled” or “not entered.”

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as “canceled” will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a “new” claim with a new claim number.

### ***Allowable Subject Matter***

17. **Claims 54-59 and 61** would be allowable if rewritten to overcome the objection(s) rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter:

No prior art teach or fairly suggest a method of implanting a device inserted into the vaginal cavity of the patient by means of vaginal surgery that comprises the steps of penetrating the tendineus arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Harris whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735

/C. H./  
Examiner, Art Unit 3735